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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/707,087	11/20/2003	Muhammed Majeed		1086

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SABINSA CORPORATION
70 ETHEL ROAD WEST
UNIT 6
PISCATAWAY, NJ 08854

EXAMINER
WEDDINGTON, KEVIN E

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)	
	10/707,087	MAJEED ET AL.	
	Examiner	Art Unit	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-9 are presented for examination.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 5-9 are rejected on the ground of nonstatutory obviousness-type

double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,804,596 in view of De Souza, "Industrial development of traditional drugs: the forskolin example a mini-review", Journal of Ethnopharmacology, Vol. 38, No. 2-3, pp. 167-175 (1993) as stated in applicants' specification in paragraph [0010].

The present application teaches a method of obesity and promoting lean body mass in a human individual in need thereof, comprising administering to the individual a lean body mass promoting composition containing effective amount of isoforskolin and or deacetylforskolin composition; and the patented application teaches a method

of promoting lean body mass in a human individual in need thereof, comprising administering to the individual a lean body promoting effective amount of forskolin. Obviously, to use the patented application to treat obesity in a human individual in need of such treatment is anticipated since an obese person does want lean body mass. The De Souza reference is used to show that plants that contains forskolin is reported to contain ladbane diterpenes like isoforskolin and deacetylforskolin, therefore, isoforskolin and deacetylforskolin possesses the same activity as forskolin. Therefore, to substitute isoforskolin in place of forskolin will promote the same lean body mass effective amount in the absence of evidence to the contrary.

Claims 1-3 and 5-9 are not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating obesity and promoting lean body mass in a human individual in need thereof with an effective amount of isoforskolin and/or deacetylforskolin composition, does not reasonably provide enablement for controlling cellulite and for improving skin tone, texture and cellular rejuvenation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method of alleviating obesity and promoting lean body mass in a human individual in need thereof, comprising administering to the individual a lean body mass promoting composition containing effective amount of isoforskolin and/or deacetylforskolin composition can also be used in cosmeceutical

preparations for controlling cellulite and for improving skin tone, texture and cellular rejuvenation.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown for the instant lean body mass promoting composition is used in cosmeceutical preparations for controlling cellulite and for improving skin tone, texture and cellular rejuvenation.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to the administration of isoforskolin and/or deacetylforskolin to treat obesity and promote lean body mass in a human in need thereof.

No examples showing the instant active ingredients formulated into a cosmeceutical preparation for controlling cellulite and for improving skin tone, texture and cellular rejuvenation.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how isoforskolin and/or deacetylforskolin can control cellulite and improve skin tone, texture and cellular rejuvenation. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claim 4 is not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered indefinite by the use of the word "alleviating" which fails to make it clear how can the instant active ingredient(s) relieve a human from obesity. The remaining claims 2-9 are rendered indefinite to the extent that they incorporate the above terminology.

Claims 1-9 are not allowed.

To overcome this rejection, the applicants may wish to delete the word "alleviating" and insert -treating--.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each

claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeed et al. (5,804,596) in view of De Souza, "Industrial development of traditional drugs: the forskolin example a mini-review", Journal of Ethnopharmacology, Vol. 38, No. 2-3, pp. 167-175 (1993) and further in view of Sears et al. (4,476,140), Morazzoni et al. (5,902,823), Greenway, III et al. (4,525,359) and Majeed et al. (6,960,300 B2).

Majeed et al. (5,804,596) teach a method of promoting lean body mass in an individual with administering of a lean body mass promoting effective amount of forskolin (see the abstract). Note the forskolin composition is from a forskolin extract of Coleus Forskohlii plant. Note particularly column 4, lines 23-25 shows the dose of from about 10 to about 60 mg. Wherein applicants' claim 2 dose falls within the range. Note column 4, lines 55-67 and columns 5 and 6 show the preparation of forskolin extract in a process of conventional solvent extraction, and purifications based on differential solubility in organic solvents.

The instant invention differs from the cited reference in that the cited reference does not teach isoforskolin and/or deacetylforskolin is used to treat obesity and promote lean body mass. However, the secondary reference, De Souza, teaches extracts from plants such as (Coleus forskohlii) containing forskolin is reported to contain ladbane diterpenes like isoforskolin and deacetylforskolin. Clearly, one skilled in the art would have assumed that isoforskolin and deacetylforskolin possesses the

same activity as forskolin. Therefore, to substitute isoforskolin in place of forskolin will promote the same lean body mass effective amount in the absence of evidence to the contrary.

The instant invention differs from the cited references in that the cited references do not teach the isoforskolin and/or deacetylforskolin can be formulated into oral administrations such as tablets, suspensions, and topicals. However, tertiary references, such as Sears et al. teach forskolin in a topical suspension; Greenway, II et al. teach forskolin as a weight control agent in topical applications; and Morazzoni et al. teach forskolin can formulated into tablets. Clearly, the tertiary references shows the various modes of administration that forskolin, which contains isoforskolin, can be formulated into.

Finally, the instant invention differs from the cited references in that the cited references do not teach the instant composition containing isoforskolin and/or deacetylforskolin can be formulated in cosmeceutical preparations. However, Majeed et al. (6,960,300) teach diterpenes such as forskolin and its congeners, analogs and derivatives can be formulated in topical and systemic use as pharmaceutical, cosmeceutical and nutraceutical preparations. Note particularly column 8, Example 10, states isoforskolin can be used in place of forskolin, clearly suggesting the substitution of active ingredients is old and well-known in the art.

Claims 1-9 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
January 30, 2006